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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,209	11/08/2007	Jeffrey L. Southard	560252000700	2819

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,209	SOUTHARD ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *3,4,17,20-29 and 33-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5-16, 18, 19, 31, 32* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/17/2008, 05/26/2009, 05/12/2010 .

DETAILED ACTION

Restriction/Election

1. Applicant's election without traverse of Group I, claims 1-15 (in part), 16, 18-36 (in part), drawn to a method of treating heart failure in a patient, comprising delivering to said patient CGRP in an amount effective to provide symptomatic relief, wherein said CGPR is delivered to said patient as a controlled release composition, in the reply filed on 05/121/2010 is acknowledged. Applicants also elected species a flowable thermoplastic polymer composition, as recited in claims 2 and 32. Claims 1-47 are pending. Claims 1, 2, 5-16, 18, 19, and 30-32 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species.

Information Disclosure Statement

2. The information disclosure statements filed on 11/17/2008, 05/26/2009, 05/12/2010 have been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Claim Rejections—35 USC § 112, 1st paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 5-16, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating heart failure in a patient comprising delivering a flowable thermoplastic polymer composition comprising CGRP to provide symptomatic relief or delay the progression of the disease state of heart failure, does not reasonably provide enablement for a method of treating heart failure in a patient comprising delivering a flowable thermoplastic polymer composition comprising CGRP to preventing exacerbation of symptoms or prevent progression of the disease state of heart failure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1, 2, 5-16, 18, and 19 are drawn, in part, to a method of treating heart failure in a patient comprising delivering a controlled release composition comprising CGRP to provide symptomatic relief, prevent exacerbation of symptoms, prevent or delay the progression of the disease state of heart failure. While the prior art (see, e.g., Gennari et al, Cardiovascular Research 24:239-241, 1990; Chandra et al., Am.

J. Cardiol. 67:732-736, 1991; EP 0845269 A2, March 6, 1998) and the instant disclosure show that administering composition CRGP can be used to treat heart failure, there are no teachings in the prior art on preventing exacerbation of symptoms or prevent progression of the disease state of heart failure. The specification does not provide working examples or guidance with respect to how to prevent exacerbation of symptoms or prevent progression of the disease state of heart failure.

Accordingly, the instant disclosure fails to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim Rejections—35 USC § 102 (b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 15, 16, 18, and 31 are rejected under 35 U.S.C. 102 (b) as being anticipated by Wo et al. (EP 0845269 A2, March 6, 1998).

Wo teaches a method for treating hypertension and congestive heart failure of a human comprising administering to the patient a pharmaceutical composition of liposomal hCGRP by intravenous infusion, oral, nasal mucosal spray in an amount of

0.1-10 pg hCGRP per kg body weight (see, e.g., Abstract, page 2, lines 37-40). Wo also teaches that this liposomal hCGRP can release hCGRP gradually from the liposome to achieve long-term effect with half-life of 72 min in vivo (page 2, lines 13-14). Thus, the teachings of Wo et al. meet the limitations of claims 1, 15, 16, 18, and 31.

Claim Rejections under 35 USC § 103(a)

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wo et al. (EP 0845269 A2, March 6, 1998).

Wo teaches a method for treating hypertension and congestive heart failure of a human comprising administering to the patient a pharmaceutical composition of liposomal hCGRP by intravenous infusion, oral, nasal mucosal spray in an amount of 0.1-10 pg hCGRP per kg body weight as applied to claims 1, 15, 16, 18, and 31 above.

Wo does not teach that the patient is a pediatric patient. However, it would have been obvious to one of skilled in the art to apply the method to treat a pediatric patient with a reasonable expectation of success. One would have been motivated to

do so because the method of treatment of Wo has beneficial effects such as gradual release, easy absorption, and bioavailability of liposomal hCGRP (page 10, lines 30-35).

9. Claims 2, 5, 9-11, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wo et al. (EP 0845269 A2, March 6, 1998) as applied to claims 1, 15, 16, 18, and 31 above, and further in view of Chandrashekar et al. (U.S. Patent No. 6,143,314, Nov. 7, 2000).

Wo teaches a method for treating hypertension and congestive heart failure of a human comprising administering to the patient a pharmaceutical composition of liposomal hCGRP by intravenous infusion, oral, nasal mucosal spray in an amount of 0.1-10 pg hCGRP per kg body weight as applied to claims 1, 15, 16, 18, and 31 above.

Wo does not teach that CGRP is delivered to a patient as a controlled release composition, which comprises a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent and CGRP.

Chandrashekar et al. teach controlled release polymeric composition comprising a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent, a polymeric controlled release additive and a biologically active agent (column 1, lines 46-54; bottom of column1 to top of column 2; column 7, the 3rd paragrpah). The biologically active agents include growth factors, hormones, cardiovascular agents (column 6, the 3rd paragraph to the first paragraph of column 7). The biologically active agent is released from the solid matrix by

diffusion or dissolution from within the polymeric matrix and/or by the degradation of the polymeric matrix (column 2, lines 11-14). The composition can be applied to a patient's tissue by any convenient technique, for example, injecting (column 7, line 53). The biocompatible polymer includes polylactides, polyglycolides, polyanhydrides and other polymers listed in claim 9 (column 3, the 3rd paragraph).

Therefore, it would have been obvious to one of skilled in the art to modify the method of Wo et al. to administer to a human patient a flowable thermoplastic polymer composition comprising CGRP to treat hypertension and congestive heart failure with a reasonable expectation of success. One would have been motivated to do so because a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent provides an alternative approach to deliver CGRP in a manner of controlled release as taught by Chandrashekar et al.

Claim Objection—Minor Informalities

10. Claims 1, 15, 16, 18, 19, and 31 are objected to because they recite non-elected subject matter (non-elected species). Claims 1, 30, and 31 are objected to because they recite "and/or". Appropriate correction is required.

Conclusion

11. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
July 19, 2010